

PTO/SB/08a/b (05-03)

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Substitute for form 1449/PTO				C mplete If Kn wn	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/688,061
				Filing Date	October 16, 2003
				First Named Inventor	Amedeo LEONARDI, et al.
				Art Unit	
				Examiner Name	TBA
Sheet	1	of	3	Attorney Docket Number	04266/100M192-US4

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.†	Document Number Number-Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
RC	1.	US 4,294,832	10-13-1981	Yoneda et al.	
RC	2.	US 4,344,949	08-17-1982	Hoefle et al.	
RC	3.	US 4,350,633	09-21-1982	Kim et al.	
RC	4.	US 4,350,704	09-21-1982	Hoefle et al.	
RC	5.	US 4,555,502	11-26-1985	Patchett et al.	
RC	6.	US 4,705,797	11-10-1987	Nardi et al.	
RC	7.	US 4,772,621	09-20-1988	Nardi et al.	
RC	8.	US 4,931,430	06-05-1990	Sudilovsky et al.	
RC	9.	US 4,931,464	06-05-1990	Grover et al.	
RC	10.	US 4,968,832	11-06-1990	Nardi et al.	
RC	11.	US 5,037,821	08-06-1991	Horovitz	
RC	12.	US 5,098,910	03-24-1992	Becker et al.	
RC	13.	US 5,696,139	12-09-1997	Leonardi et al.	
RC	14.	US 5,767,136	06-16-1998	Sartani et al.	
RC	15.	US 5,912,351	06-15-1999	Leonardi et al.	
RC	16.	US 6,086,919	07-11-2000	Bauer et al.	
RC	17.	US 6,110,684	08-29-2000	Kemper et al.	
RC	18.	US 6,183,958	02-06-2001	Stanton Jr.	
RC	19.	US 6,200,754	03-13-2001	Housman et al.	
RC	20.	US 2003/0180355 A1	09-25-2003	Leonardi et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
RC	21.	CA 2 070 085 ✓	12-01-1992	Polli		
RC	22.	DE 3 437 917 ✓	04-17-1986	Bayer AG		
RC	23.	DE 3 633 496 ✓	04-14-1988	Hoechst AG		
RC	24.	DE 3 736 505 ✓	05-05-1988	Sandoz-Patent-Gmbh		
RC	25.	DE 4 109 134 ✓	09-24-1992	Knoll AG		
RC	26.	DE 4 141 646	06-24-1993	Klinge Pharma mbh & Co KG		
RC	27.	DE 4 308 504 ✓	09-22-1994	Knoll AG		
RC	28.	EP 259 838 ✓	03-16-1988	Syntex (USA) Inc.		
RC	29.	EP 272 177	06-22-1988	Synthelabo		
RC	30.	EP 331 803	09-13-1989	Squibb ER & Sons Inc.		
RC	31.	EP 334 264 ✓	09-27-1989	Squibb ER & Sons Inc		
RC	32.	EP 344 995 ✓	12-06-1989	Squibb ER & Sons Inc		

Examiner Signature	/Renee Claytor/	Date Considered	11/20/2006
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				First Named Inventor	Amedeo LEONARDI, et al.
				Art Unit	
				Examiner Name	TBA
Sheet	2	of	3	Attorney Docket Number	04266/100M192-US4

RC	33.	EP 381 075 ✓	08-08-1990	Squibb ER & Sons Inc		
RC	34.	EP 795 327 ✓	09-17-1997	Pfizer Inc		
RC	35.	EP 884 054 ✓	12-16-1998	Vita-Invest SA		
RC	36.	FR 2 733 911 ✓	11-15-1996	Takeda Chem Ind Ltd		
RC	37.	WO 96/07400 ✓	03-14-1996	Astra AB		
RC	38.	WO 98/45477	10-15-1998	Eurona Medical AB		
RC	39.	WO 01/76632 ✓	10-18-2001	Wald and Law		
RC	40.	WO 02/34303 ✓	05-02-2002	Nitromed, Inc.; Trustees of Boston Univ.		

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ²
RC	41.	Aranda et al., (2000) "Therapeutic Efficacy and Tolerability of Lercanidipine Versus Candesartan, Alone or in Combination, in Mild-Moderate Essential Hypertensives", <i>Journal of Hypertension</i> , 18(suppl. 2):S152				
RC	42.	Cleophas et al., (2001) "Diabetics with Hypertension Not Controlled with ACE Inhibitors: Alternate Therapies", <i>Angiology</i> , 52:469-475				
RC	43.	Gasser et al., (1999) "Lercanidipine, a new third generation Ca-antagonist in the treatment of hypertension", <i>J Clin Basic Cardiol</i> , 2:169-174				
RC	44.	Grandi et al., (2002) "Aldosterone Antagonist Improves Diastolic Function in Essential Hypertension", <i>Hypertension</i> , 40:647-652				
RC	45.	Mancia et al., (1998) "Clinical Advantages of Lipophilic Dihydropyridines", <i>Blood Pressure</i> , 7(suppl 2):23-26				
RC	46.	Mancia and Grassi (1994) "Combination treatment of hypertension", <i>High Blood Pressure</i> , 3 (suppl to No. 4): 5-7				
RC	47.	McClellan and Jarvis (2000) "Lercanidipine: A Review of its Use in Hypertension", <i>Drugs</i> , 60:1123-1140				
RC	48.	Menard and Bellet (1993) "Calcium Antagonists-ACE Inhibitors Combination Therapy: Objectives and Methodology of Clinical Development", <i>J of Cardiovascular Pharmacology</i> , 21(supp. 2):S49-S54				
RC	49.	Omboni and Zanchetti (1998) "Antihypertensive efficacy of lercanidipine at 2.5, 5 and 10mg in mild to moderate essential hypertensives assessed by clinic and ambulatory blood pressure measurements", <i>J Hypertens</i> , 16:1831-1838.				
RC	50.	Ramsay et al., (1999) "Guidelines for management of hypertension: report of the third working party of the British Hypertension Society", <i>J of Human Hypertension</i> , 13:569-592				

Examiner Signature	/Renee Claytor/	Date Considered	RC
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				Application Number	10/688,061
				Filing Date	October 16, 2003
				First Named Inventor	Amedeo LEONARDI, et al.
				Art Unit	
				Examiner Name	TBA
Sheet	3	of	3	Attorney Docket Number	04266/100M192-US4

RC	51.	Recordati et al. (2000) "Effects of a reversible 'nephrectomy' on renal sympathetic activity and blood pressure in the rat: evidence for an acute angiotensin-mediated hypertension", <i>Journal of Hypertension</i> , 18:1277-1287	
RC	52.	Rengo and Romis (1997) "Activity of Lercanidipine in Double-Blind Comparison with Nitrendipine in Combination Treatment of Patients with Resistant Essential Hypertension", <i>J of Cardiovascular Pharmacology</i> , 29(suppl 2):S54-S58	
RC	53.	van Zwieten (2000) "The influence of antihypertensive drug treatment on the prevention and regression of left ventricular hypertrophy", <i>Cardiovascular Research</i> , 45:82-91	
RC	54.	Weir AJH (1998) "The Rationale for Combination Versus Single-Entity Therapy in Hypertension", <i>American Journal of Hypertension</i> , 11:163S-169S	

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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Renee Claytor/	Date Considered	11/20/2006
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PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0851-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete If Known	
				Application Number	10/688,061-Conf. #8154
				Filing Date	October 16, 2003
				First Named Inventor	Amedeo Leonardi
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	04266/100M192-US4

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
RC	BA	WO-99/11260-A1	03-11-1999	Pfizer Inc.		

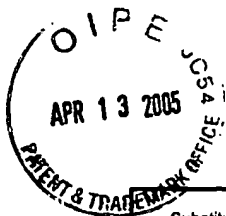
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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				Application Number	10/688,061
				Filing Date	October 16, 2003
				First Named Inventor	Amedeo Leonardi
				Art Unit	1626
				Examiner Name	TBA
Sheet	1	of	1	Attorney Docket Number	04266/100M192-US4

U.S. PATENT DOCUMENTS					
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RC	A	6,852,737	02/08/2005	Bonifacio, et al.	
RC	B	6,162,802	12/19/2000	Papa, et al.	
RC	C	6,086,919	07/11/2000	Bauer, et al.	
RC	D	2003/0069285	04/10/2003	Amedeo, et al.	

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RC	1	WO 03/097067	11/27/2003	Novartis AG	

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RC	2	Epstein, MD, Murray (2001), "Lercanidipine - A Novel Dihydropyridine Calcium-Channel Blocker," <i>Heart Disease</i> 3: 398-407	
RC	3	Martell, N. (2003) "Association of Lercanidipine Plus Enalapril to Control Blood Pressure," presented at the Amercian Society of Hypertension, May 14-17, 2003, New York, NY (Abstract)	
RC	4	Messerli, MD, Franz (2002), "Vasodilatory Edema: A Common Side Effect of Antihypertensive Therapy," <i>Current Cardiology Reports</i> 4: 479-482	
RC	5	Morgan, Trefor et al. (2002), "A Comparison of Candesartan, Felodipine, and Their Combination in the Treatment of Elderly Patients with Systolic Hypertension," <i>American Journal of Hypertension</i> 15(6): 544-549	
RC	6	Ruzicka, MD, Marcel et al. (2002), "Combination therapy as first-line treatment of arterial hypertension," <i>Can. J. Cardiol.</i> 18(12): 1317-1327	

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		Application Number	10/688,061		
		Filing Date	April 28, 2004		
		First Named Inventor	Amedeo Leonardi		
		Art Unit	1623		
		Examiner Name	TBA		
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RC	1	Martell et al. (2002) "Asociaciones Terapéuticas en El Control de la Presión Arterial," Poster and Abstract presented at the 7 th Reunión Nacional Sociedad Española de Hipertensión Liga Española para la Lucha contra la Hipertensión Arterial, <i>Hipertensión</i> 19(2), Abstract 61T	
RC	2	Martell et al. (2002) "Asociaciones Farmacologicas en Hipertensos con Factores de Riesgo Cardiovascular," Poster and Abstract presented at the 7 th Reunión Nacional Sociedad Española de Hipertensión Liga Española para la Lucha contra la Hipertensión Arterial, <i>Hipertensión</i> 19(2), Abstract 69T	

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